

Pedicle screw insertion accuracy with different assisted methods: a systematic review and meta-analysis of comparative studies

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Abstract Studies revealed that navigation systems that provided intraoperative assistance might improve pedicle screw insertion accuracy, and also implied that different systems provided different pedicle screw insertion accuracy. A systematic review and meta-analysis was conducted to focus on the pedicle screw insertion accuracy with or without the assistance of image-guided system, and the variance among the different navigation systems. Comparative studies were searched on pedicle screw insertion accuracy between conventional and navigated method, and among different navigation systems. A total of 43 papers, including 28 clinical, 14 cadaveric and 1 model studies, were included in the current study. For clinical articles, there were 3 randomized clinical trials, 4 prospective comparative studies and 21 retrospective comparative studies. The incidence of pedicle violation among computer tomography-based navigation method group was statistically significantly less than that observed among the conventional group (OR 95% CI, in vivo: 0.32–0.60; in vitro: 0.24–0.75 $P < 0.01$). Two-dimensional fluoroscopy-based navigation system (OR 95% CI, in vivo: 0.27–0.48; in vitro: 0.43–0.88 $P < 0.01$) and three-dimension fluoroscopy-based navigation system (OR 95% CI, in vivo: 0.09–0.38; in vitro: 0.09–0.36 $P < 0.01$) also obtained significant reduced screw deviation rate over traditional methods. Between navigated approaches, statistically insignificant individual and pooled RR values were observed for all in vivo subgroups. Pooled estimate of in

vitro studies show that computer tomography-based and three-dimension fluoroscopy-based navigation system provided more accurate pedicle screw insertion over two-dimension fluoroscopy-based navigation system. Our review showed that navigation provided a higher accuracy in the placement of pedicle screws compared with conventional methods. The superiority of navigation systems was obvious when they were applied to abnormal spinal structure. Although no strong in vivo evidence has detected significantly different pedicle screw placement accuracy among the three major navigation systems, meta-analysis revealed the variance in pedicle screw insertion accuracy with different navigation methods.

Keywords Navigated spine surgery · Pedicle screw · Computer tomography · Fluoroscopy · Accuracy

Introduction

On account of its three-column control and good fixation for the vertebral body, transpedicle screw fixation has been widely used in spinal surgeries [1, 8–56]. However, pedicle violation resulted from malpositioned screw leading to potential harm to nearby vital structures, which prompted surgeons to search for the perfect strategy. Though alternative methods (e.g., transarticular screw [2], lateral mass [3], extrapedicular screw fixation [4, 5]) were developed for better surgical outcome, surgeons were more prone to improve the pedicle screw insertion accuracy by trying various supporting methods (e.g., intraoperative monitoring [6, 7], anatomical markers [13, 24, 26, 47]). Nevertheless, none of the conventional methods was considered as the perfect intraoperative assisting method.

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Many researches have revealed that navigation systems that provided intraoperative assistance obtained the potential to improve pedicle screw insertion accuracy [11, 13, 15, 17, 19, 22–24, 26, 28, 32, 33, 35, 36, 39, 41, 44–50, 54, 55]. Studies also implied that different power was observed in providing pedicle screw insertion accuracy among various navigational methods [11–13, 15, 30, 39–41, 49, 55]. No matter which method was used to assist pedicle screw insertion, surgeons cared more about the placing accuracy, because surgical outcomes such as neurological complications and health outcome scores were usually correlated with the screw insertion accuracy. As a result, the primary purpose of current analysis was to assess the accuracy of pedicle screw placement with different assisting methods. We focused on the application of navigation systems in the pedicle screw insertion surgeries and the difference of pedicle screw placement accuracy between navigated and conventional method, and the variance among the different navigation systems.

Methods

As a small number of randomized controlled trials were anticipated, comparative studies (prospective and retrospective) were also included in the current review. Inclusion criteria were established before the search. To be included in the study, the following criteria were used: (1) the paper must include a navigated pedicle screw insertion comparative design; (2) pedicle screw placement accuracy was to be analyzed. Exclusion criteria were: (1) pedicle screw inserted but no navigation employed or applied, and no postoperative accuracy assessment conducted; (2) repetitive studies.

A literature search was conducted spanning from January 1990 to May 2010 using OVID, Springer, EMBASE, MEDLINE and China National Knowledge Infrastructure databases. We screened the title, subtitle and abstract by combining the term pedicle screw with each of the following keywords: computer assisted/assistance/aided, image guided/guiding/guidance, navigation and navigated. A manual search of reference lists of previous systematic reviews and relevant trials was conducted.

Two reviewers (Z.P, Z.Y.) independently extracted data using a standardized form. Inconsistencies between reviewers' data were resolved through discussion until a consensus was reached. Papers obtained were categorized into levels of evidence according to those published in the Journal of Bone and Joint Surgery (American).

We extracted data on study design, patient characteristics, interventions, outcome measurements (pedicle screw violation) and conclusions from the original papers. In the current review, a unified method was used to extract pedicle screws

that were inserted without deviation from total screws of each study (if such data were not available, we extracted the pedicle screws that were most perfectly inserted based on the researchers' definition). Pedicle violation rate was summarized using relative risk (RR) and 95% confidence intervals (CIs). The level of significance was set at $P < 0.05$. Heterogeneity was evaluated by using the χ^2 test. A value of $P < 0.1$ was considered to be significant for heterogeneity. Fixed-effect models were used unless statistical heterogeneity was significant, in which case a random-effects model was used. Analysis was performed using the statistical software Review Manager Version 4.2 (Cochrane Collaboration, Software Update, Oxford, UK).

Results

The search strategy resulted in 89 studies, which used navigated pedicle screw insertion design and had insertion accuracy assessed. Of these, 46 were excluded because they were case series. The remaining 43 papers [11–51, 54, 55] included 28 clinical [12–38, 55], 14 cadaveric [39–51, 54] and 1 model [11] study. Based on study design, the clinical articles could be classified into 3 randomized clinical trials [18, 23, 37], 4 prospective comparative studies [22, 25, 27, 29] and 21 retrospective comparative studies [12–17, 19–21, 24, 26, 28, 30–36, 38, 55].

Analysis

Navigation methods for pedicle screw insertion

Since the introduction of navigation techniques into the field of orthopedic surgery, the surgical methods for this area have been greatly increased. Based on intraoperative assisting method, computer-assisted surgery could be subclassified into three types including volumetric image-based navigation, fluoroscopic navigation and imageless navigation [57]. The first one uses preoperative images such as CT and MRI, while the second one utilizes intraoperative two-dimensional or three-dimensional fluoroscopic images. Imageless navigation makes use only of intraoperative anatomical information and is mainly employed to assist total hip/knee arthroplasty [57]. In our review, we found three major navigation systems that had been used to assist pedicle screw insertion including computer tomography-based navigation system (CT Nav), two-dimension fluoroscopy-based navigation system (2D FluoroNav) and three-dimension fluoroscopy-based navigation system (3D FluoroNav). CT Nav requires preoperative CT scan of the target bone. The data have to be transferred to the navigational system. After matching and registration, the

preoperative anatomical information is then used to assist pedicle screw insertion. In contrast to CT Nav, 2D FluoroNav does not need registration. It uses intraoperative two-dimensional images and provides real-time intraoperative visualization of spinal anatomy. With the development of the 3-D C-arm, 3D FluoroNav gradually gained popularity in spinal surgeries. Though its image quality is lower than that of CT, 3D FluoroNav provides real-time three-dimensional images, which serves as both C-arm and CT-based navigation, and does not need registration [57, 58].

Meta-analysis for pedicle screw insertion accuracy

Kosmopoulos and Schizas [8] conducted a meta-analysis by pooling published literature studying the accuracy of pedicle screw placement in the human spine with or without the assistance of navigation systems. By using a descriptive statistical method, the study revealed that the median placement accuracy for the *in vivo* assisted navigation subgroup was higher than that of the subgroup without the use of navigation. Navigation provided a higher accuracy in the placement of pedicle screws for most of the subgroups presented. In a pooled analysis of 14 comparative studies on pedicle screw insertion, Verma et al. [56] also demonstrated a significant advantage in terms of accuracy of navigation over conventional methods. The limitation was that the two reviews analyzed different navigation methods together, and drew pooled navigated pedicle screw insertion accuracy. The concerns regarding these studies were whether there was any difference among various navigation methods and whether each of them provided better screw insertion over conventional methods. The questions lead to our reanalysis.

In the present study, based on the study population and navigation method, the incidence of pedicle violation among the computer tomography-based navigation method group was statistically significantly less than that observed among the conventional group (OR 95% CI, *in vivo*: 0.32–0.60; *in vitro*: 0.24–0.75, $P < 0.01$). Two-dimensional fluoroscopy-based navigation system (OR 95% CI, *in vivo*: 0.27–0.48; *in vitro*: 0.43–0.88, $P < 0.01$) and three-dimensional fluoroscopy-based navigation system (OR 95% CI, *in vivo*: 0.09–0.38; *in vitro*: 0.09–0.36, $P < 0.01$) also obtained significant reduced screw deviation rate over traditional methods. In conclusion, both *in vivo* and *in vitro* subgroups revealed that navigation method obtained a significant lesser pooled risk of pedicle violation compared with the conventional method ($P < 0.05$). The results were consistent with those of Kosmopoulos and Schizas, Verma et al. [8, 56] (Fig. 1). In our previous meta-analysis [9], we analyzed the accuracy of pedicle screw insertion with different navigation methods using a similar method as Kosmopoulos and Schizas

[8]. The median placement accuracy for the CT-based navigation subgroup was higher than that with the use of 2D FluoroNav for both *in vivo* and *in vitro* subgroups. *In vivo* subgroup analysis indicated that 3D FluoroNav obtained the most improved screw insertion accuracy. In the current study, the pooled RR values also indicated that CT Nav provided a little higher accuracy than the 2D FluoroNav subgroup (CT Nav vs. 2D FluoroNav: *in vivo* OR = 0.64, $P > 0.05$; *in vitro* OR = 0.37, $P < 0.05$), but provided a lower accuracy than the 3D FluoroNav subgroup (3D FluoroNav vs. 2D FluoroNav: *in vivo* OR = 0.65, $P > 0.05$; *in vitro* OR = 0.80, $P > 0.05$). Overall, the pooled relative risks of all *in vivo* subgroups were statistically insignificant ($P > 0.05$), whereas RR values of two *in vitro* subgroups were statistically significant ($P < 0.05$; Fig. 2; Tables 1, 2).

Computer tomography-based navigation system

CT-assisted pedicle screw insertion accuracy

The first generation of navigation applied to spinal surgery was the computer tomography-assisted system. CT image provided precise three-dimensional anatomy information, which allowed for intraoperative guidance. Many studies have indicated the potential in the use of this system [11, 13, 19, 22–24, 26, 28, 32, 35, 39, 41, 44–51]. A randomized control study was conducted including 100 patients comparing the pedicle screw insertion accuracy between conventional and CT-based navigation method [23]. The pedicle perforation rate was significantly higher in the conventional group (13.4%) compared with 4.6% in the computer-assisted group ($P = 0.006$). Pedicle perforations of more than 4 mm were found in 1.4% (4/277) of the screw insertions in the conventional group and none in the computer-assisted group, whereas another RCT conducted by Li et al. [37] reported that no significant accuracy difference was found between the conventional and navigated groups. In the current review, by reanalyzing the pedicle perforation rate of CT Nav over the conventional approaches for the *in vivo* population, except for two studies [27, 37], all papers [13, 15, 19–26, 28, 29, 32, 35, 38] implied that CT Nav obtained a lesser risk compared with the conventional methods, and nine [13, 19, 22–24, 26, 28, 32, 35] of them were statistically significant (Fig. 1). For the *in vitro* studies [11, 39, 41, 44–50], five studies [11, 41, 47, 49, 50] indicated the statistically improved accuracy (Fig. 1).

CT-assisted pedicle screw insertion in scoliosis correction surgeries

Pedicle screw fixation has gained popularity in deformity correcting surgeries, as it enables a shorter fusion length

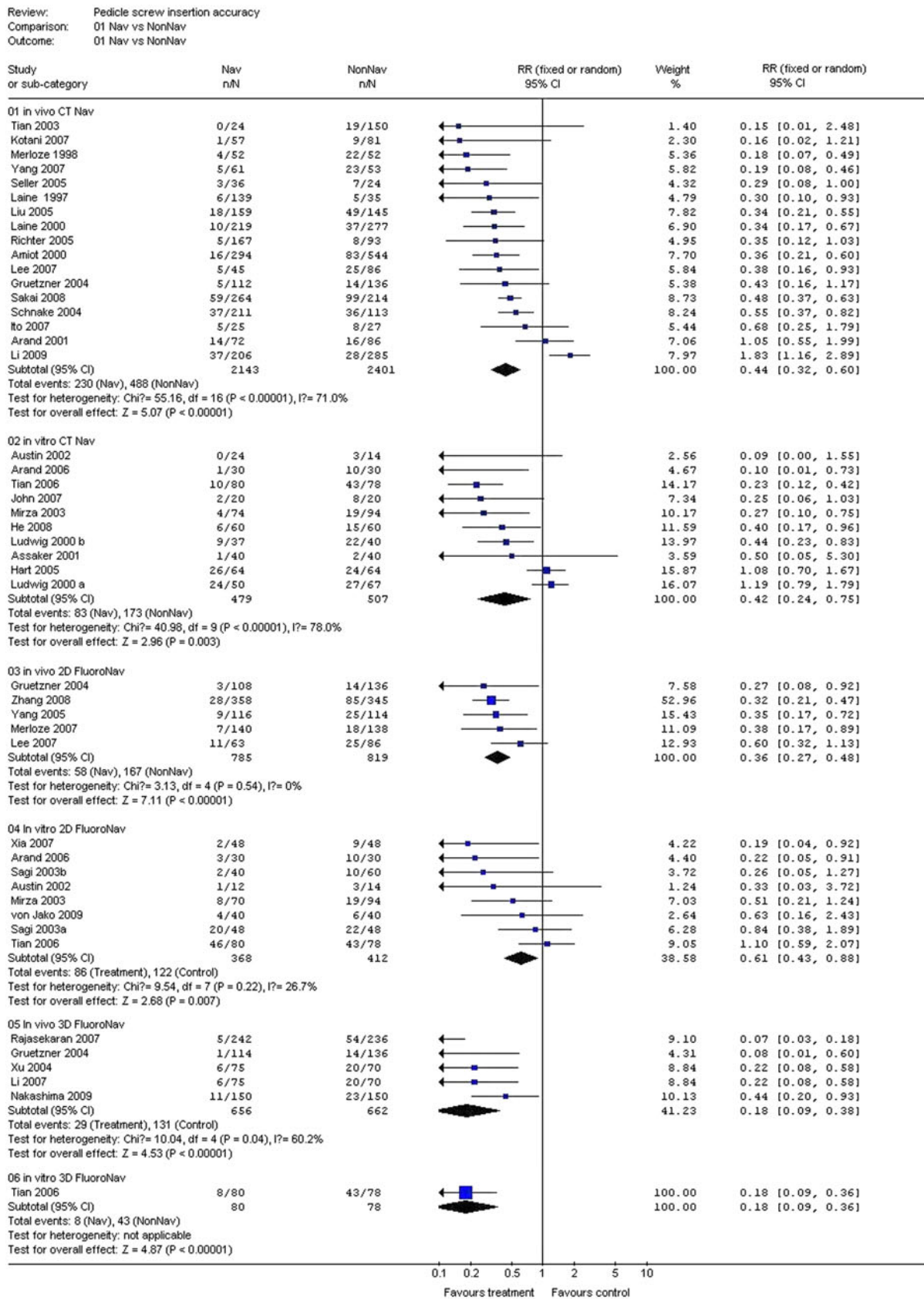


Fig. 1 Pedicle screw insertion accuracy: navigation versus non-navigation. Computed tomography-based navigation (CT Nav), two-dimensional fluoroscopy-based navigation (2D FluoroNav), and three-dimensional fluoroscopy-based navigation (3D FluoroNav)

Review: Pedicle screw insertion accuracy
 Comparison: 02 Nav vs Nav
 Outcome: 01 Nav vs Nav

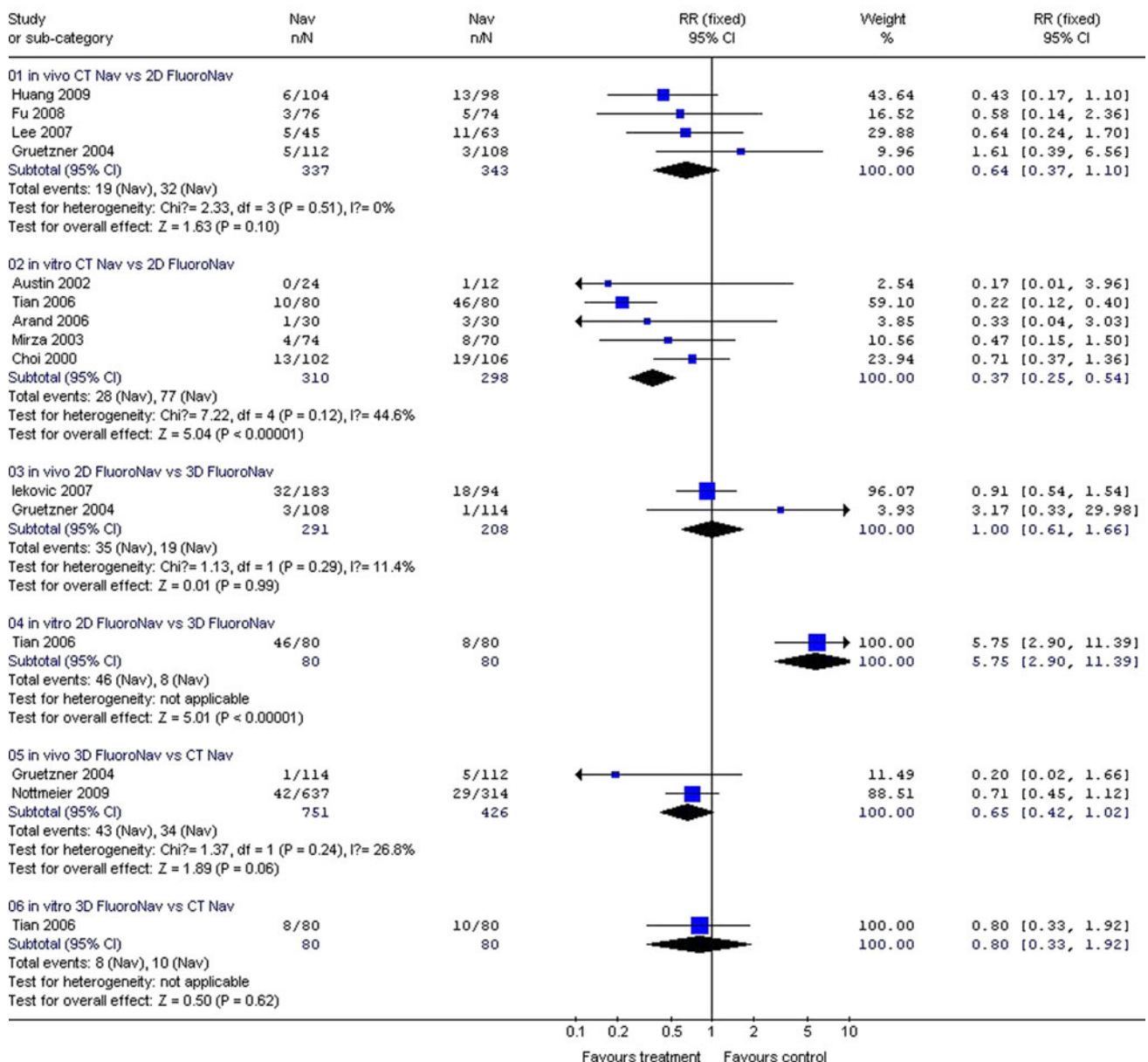


Fig. 2 Pedicle screw insertion accuracy: navigation versus navigation. Computed tomography-based navigation (CT Nav), two dimensional fluoroscopy-based navigation (2D FluoroNav), and three-dimensional fluoroscopy-based navigation (3D FluoroNav)

and a better correction. However, significant deformity increased the pedicle drift rate, which raised the potential risk to nearby neurovascular and visceral structures. To avoid screw misplacement, the CT-based navigation system was applied in many studies as it provided intraoperative three-dimensional images [10, 21, 24, 26, 35]. Merloz et al. [24] found 4 incorrectly placed screws of the 28 inserted pedicle screws for scoliosis with the help of the CT Nav, and there were no neurologic complications in all patients. In a larger population with 264 pedicle screws

inserted, only 11 were classified as total deviation based on Neo classification, and no neurovascular complications were found during or after surgery in any of the cases [10]. By comparing the pedicle screw placement accuracy in posterior scoliosis surgery between conventional fluoroscopic and computer-assisted surgical techniques in a retrospective cohort study, Kotani et al. [21] discovered that perforation was as high as 11% in the conventional group compared with only 1.8% in the navigated group. A retrospective comparative study conducted by Yang et al. [35]

Table 1 Description of included clinical studies

Study (year)	Study design (class of evidence)	Participants (spinal level)	Interventions	Accuracy assessment	Conclusions
Laine et al. [22]	Prospective comparative study (II)	30 patients: 16 male, 14 female; age: 29–73 years Spinal stenosis, instability, painful disc degeneration, spondylolysis, pseudarthrosis, kyphosis (L1–S1)	G1: CT Nav (139 screws) G2: convention (35 screws)	CT	Computer-assisted surgery is superior to the conventional method
Merloz et al. [24]	Retrospective comparative study (III)	64 patients: sex and age unstated Spondylolisthesis, scoliosis, fracture (T10–L5)	G1: convention; n = 26 (52 screws) G2: CT Nav n = 26 (52 screws) G3: CT Nav n = 12 (28 screws)	CT	Computer-assisted technique is much more accurate and safer than manual insertion
Laine et al. [23]	Randomized controlled trial (I)	91 patients: sex unstated; age: 22–82 years Spinal stenosis, post-discectomy syndrome, spondylolysis/olisthesis, disc degeneration, deformity (T8–S1)	G1: CT Nav n = 41 (219 screws) G2: convention n = 50 (277 screws)	CT	Pedicular screws were inserted more accurately with navigation than with conventional methods
Amiot et al. [19]	Retrospective comparative study (III)	150 patients: sex unstated; mean age: 48.4 years Failed back surgery, instability, tumor, spondylolisthesis, spondylodiscitis, fracture, spinal stenosis (T2–S1)	G1: convention n = 100 (544 screws) G2: CT Nav n = 50 (294 screws)	MRI	Computer assistance decreases the incidence of incorrectly positioned pedicle screws
Arand et al. [27]	Prospective comparative study (II)	Population characteristics could not be detailed extracted	G1: convention (86 screws) G2: CT Nav (72 screws)	CT	Computer-assisted freehand navigation improves results, but requires a learning curve
Tian et al. [38]	Retrospective comparative study (III)	29 patients: 18 male, 11 female; age: 26–76 years Fracture, cervical spondylotic myelopathy, OPLL (cervical)	G1: CT Nav n = 4 (24 screws) G2: convention n = 25 (150 screws)	CT X-ray	CT Nav has the potential of application in cervical spinal surgeries
Schnake et al. [28]	Retrospective comparative study (III)	85 patients (12 undergoing two surgical techniques): 55 male, 42 female; age: 16–80 years	G1: convention n = 41 (113 screws) G2: CT Nav n = 56 (211 screws)	CT	CT Nav provides more accurate pedicle screw insertion than the conventional method
Gruetzner et al. [15]	Retrospective comparative study (III)	113 patients: 75 male, 38 female; age: 16–76 years Injuries or degenerative changes to the spine (cervical, thoracic, lumbar)	G1: CT Nav n = 27 (112 screws) G2: 2D FluoroNav n = 28 (108 screws) G3: 3D FluoroNav n = 24 (114 screws) G4: convention n = 34 (136 screws)	CT	3D fluoro Nav enhances screw insertion accuracy, and requires less fluoroscopy time compared to other approaches

Table 1 continued

Study (year)	Study design (class of evidence)	Participants (spinal level)	Interventions	Accuracy assessment	Conclusions
Xu et al. [34]	Retrospective comparative study (III)	49 patients: 29 male, 20 female; age: 42–79 years Disc herniation, spinal stenosis, spondylolisthesis, scoliosis, fracture (thoracic, lumbar)	G1: 3D FluoroNav <i>n</i> = 35 (190 screws) G2: convention <i>n</i> = 14 (76 screws)	3D FluoroNav	3D FluoroNav makes pedicle screw insertion more accurate, and less time consuming
Richter et al. [25]	Prospective comparative study (II)	52 patients: sex unstated; age: 29–76 years Cervical spondylotic myelopathy, fracture, tumor, implant failure, kyphotic deformity, RA, iatrogenic instabilities (cervical)	G1: convention <i>n</i> = 20 (93 screws) G2: CT Nav <i>n</i> = 32 (167 screws)	CT	Computer-assisted surgery system leads to significantly reduced screw misplacement
Seller et al. [29]	Prospective comparative study (II)	16 patients: sex unstated; age unstated; deformity: spinal stenosis, spondylolisthesis (T12–L5)	G1: convention (24 screws) G2: CT Nav (36 screws)	CT/MRI	Computer-assisted surgery reduces the misplacement rate of pedicle screws
Liu et al. [32]	Retrospective comparative study (III)	53 patients: 33 male, 20 female; age: 23–72 years Fracture, cervical spondylotic myelopathy, deformity, OPLL, tumor (cervical)	G1: CT Nav <i>n</i> = 29 (159 screws) G2: Convention <i>n</i> = 24 (145 screws)	CT	CT-based navigation system increases accuracy of cervical pedicle screw fixation
Yang et al. [33]	Retrospective comparative study (III)	44 patients: 26 male, 18 female; age: 15–69 years Disc herniation, spinal stenosis, spondylolisthesis, scoliosis (thoracic, lumbar)	G1: 2D FluoroNav <i>n</i> = 22 (116 screws) G2: convention <i>n</i> = 22 (114 screws)	X-ray	Navigation system increases the pedicle screw insertion accuracy, and decreases radiation exposure
Lee et al. [13]	Retrospective comparative study (III)	60 patients: sex unstated; age: 21–91 years Cervical spondylotic myelopathy, trauma, deformity, infection, OPLL, RA, osteoporosis (C7, T1, T2)	G1: open technique <i>n</i> = 32 (86 screws) G2: 2D FluoroNav <i>n</i> = 19 (63 screws) G3: CT Nav; <i>n</i> = 9 (45 screws)	CT	Computer-assisted surgery allows for more accurate placement of pedicle screws at the CTJ
Lekovic et al. [14]	Retrospective comparative study (III)	37 patients: 20 male, 17 female; age: 35–81 years Trauma, degenerative disease, tumor (T1–T12)	G1: 2D FluoroNav <i>n</i> = 25 (183 screws) G2: 3D FluoroNav <i>n</i> = 12 (94 screws)	CT	Both image-guidance systems provide high degree of accuracy and safety
Merloz et al. [17]	Retrospective comparative study (III)	52 patients: 32 male; 20 female; age: 16–67 years Fracture, scoliosis, degenerative instabilities, spondylolisthesis (T8–L5)	G1: convention <i>n</i> = 26 (138 screws) G2: 2D FluoroNav <i>n</i> = 26 (140 screws)	CT X-ray	2D fluoro Nav for pedicle screw insertion is a reliable procedure for the lower thoracolumbar spine
Rajasekaran et al. [18]	Randomized controlled trial (I)	33 patients: 10 male, 23 female; age: 10–52 years Scoliosis, kyphosis (thoracic, lumbar)	G1: convention <i>n</i> = 16 (236 screws) G2: 3D FluoroNav <i>n</i> = 17 (242 screws)	CT	3D fluoro Nav increases accuracy, reduces surgical time and radiation in deformity correction surgeries

Table 1 continued

Study (year)	Study design (class of evidence)	Participants (spinal level)	Interventions	Accuracy assessment	Conclusions
Ito et al. [20]	Retrospective comparative study (III)	10 patients: 1 male, 9 female; age: 29–70 years Rheumatoid arthritis (RA) (C2–C6)	G1: CT Nav <i>n</i> = 5 (25 screws) G2: convention <i>n</i> = 5 (27 screws)	CT	Navigation enhances pedicle screw insertion in RA patients, even if it requires more time
Kotani et al. [21]	Retrospective comparative study (III)	45 patients: 8 male, 37 female; age: 6–33 years Scoliosis (thoracic, lumbar)	G1: CT Nav <i>n</i> = 20 (57 screws) G2: convention <i>n</i> = 25 (81 screws)	CT	Navigation system reduces the perforation rate and insertion angle errors
Li [31]	Retrospective comparative study (III)	35 patients: 23 male, 12 female; age: 23–76 years Fracture, cervical spondylotic myelopathy, deformity, OPLL (cervical)	G1: 3D FluoroNav <i>n</i> = 15 (75 screws) G2: convention <i>n</i> = 20 (76 screws)	3D FluoroNav	3D FluoroNav increases the accuracy of cervical pedicle screw implantation significantly
Yang et al. [35]	Retrospective comparative study (III)	10 patients: 3 male, 7 female; age: 13–59 years Scoliosis (thoracic, lumbar)	G1: CT Nav <i>n</i> = 5 (61 screws) G2: convention <i>n</i> = 5 (53 screws)	CT radiograph	CT Nav enhances accuracies and further improves the safety of adolescent scoliosis surgery
Zhang et al. [36]	Retrospective comparative study (III)	132 patients: 63 male, 69 female; mean age: 44.8 years Disc herniation, spinal stenosis, spondylolisthesis, scoliosis, fracture (thoracic, lumbar)	G1: 2D FluoroNav <i>n</i> = 66 (358 screws) G2: convention <i>n</i> = 66 (345 screws)	CT X-ray	2D FluoroNav offers more accurate pedicle screw placement than traditional operation
Fu et al. [12]	Retrospective comparative study (III)	24 patients: 9 male, 15 female; age: 19–79 years Fracture, spondylolisthesis, tuberculous spondylitis, ankylosing spondylitis, revision (below T8 level)	G1: 2D FluoroNav <i>n</i> = 13 (74 screws) G2: CT Nav <i>n</i> = 11 (76 screws)	CT	Navigation provides accuracy for screw placement, and 2D fluoro Nav offers real-time and simple usage
Sakai et al. [26]	Retrospective comparative study (III)	40 patients: 8 male, 32 female; mean age: 14.8 years Idiopathic scoliosis (thoracic, lumbar)	G1: convention <i>n</i> = 20 (214 screws) G2: CT Nav <i>n</i> = 20 (264 screws)	CT	Navigation system reduces the screw misplacement for rotated vertebrae
Nottmeier et al. [16]	Retrospective comparative study (III)	220 patients: sex and age unstated; spinal disease unstated (T1–S1)	G1: 3D FluoroNav <i>n</i> = 140 (637 screws) G2: CT Nav <i>n</i> = 80 (314 screws)	CT	3D navigation improves screw insertion, and has less radiation exposure
Li et al. [37]	Randomized controlled trial (I)	95 patients: 45 male, 50 female; age: 12–75 years Tumor, kyphosis, spinal stenosis, spondylolisthesis, scoliosis (spinal level unstated)	G1: CT Nav <i>n</i> = 36 (206 screws) G2: convention <i>n</i> = 50 (285 screws)	CT	CT Nav produces similar accuracy of screw insertion, but has prolonged operation time

Table 1 continued

Study (year)	Study design (class of evidence)	Participants (spinal level)	Interventions	Accuracy assessment	Conclusions
Huang et al. [30]	Retrospective comparative study (III)	42 patients: 29 male, 13 female; age: 24–64 years Fracture, spondylolisthesis, lumbar disc herniation (thoracic, lumbar)	G1: 2D FluoroNav $n = 21$ (98 screws) G2: CT Nav $n = 21$ (104 screws)	CT X-ray	Navigation systems improve pedicle screw placing, but CT Nav needs more surgical time
Nakashima et al. [55]	Retrospective comparative study (III)	67 patients: 50 male, 17 female; mean age, 52–84 years Degenerative spondylolisthesis with lumbar spinal canal stenosis	G1: 3D FluoroNav (150 screws) G2: convention (150 screws)	CT	It is feasible to place percutaneous posterior lumbar pedicle screws with 3D FluoroNav

in ten patients also revealed that CT-based navigation significantly enhanced the accuracy of pedicle screw insertion in adolescent scoliosis patients. Another paper reported that the pedicle violation rate was 28.0% in the control group and 11.4% in the navigation group; it was noteworthy that the difference was statistically significant, though a much higher pedicle violation rate was detected for both groups compared with other similar studies [26]. Overall, CT-based navigation provided a higher accuracy in scoliosis correction surgeries and avoided potential risk to vital structure, which might result from intraoperative visual anatomy of the abnormal pedicles.

CT-assisted pedicle screw insertion into previously fused spines

Many conventional methods usually relied on crucial anatomic landmarks to place the screw into the pedicle [13, 24, 26, 47]. As a result, it would be a challenge when the pedicle screw was to be inserted through a posterolateral fusion mass, where the traditional posterior spinal landmarks were often obscured or completely absent and the tactile feedback from the native cortical/cancellous bone was lost. CT-based navigation was able to generate multiplanar cross-sectional images that provided intraoperative visualization of cross-sectional anatomy, which would not be interfered by abnormal structures [39, 52]. In vitro test verified the great potential of applying the systems in such cases. Austin et al. [35] compared conventional open laminoforaminotomy and two image-guided (CT Nav and 2D FluoroNav) techniques for pedicle screw placement in posterolateral fusion and nonfusion models. The study showed that the accuracy of pedicle screw placement was improved with the use of image-guided methods, particularly guidance by computed tomography. It was noteworthy that all screws in the study were accurately inserted without deviation from the fusion mass group with CT assistance [35]. In a clinical study, the system also obtained improved results: Lim et al. [52] analyzed the postoperative CT scans of 35 patients and found only 5 (4.1%) of the 122 pedicle screws placed into previously fused levels having unintentional cortical violations.

Two-dimension fluoroscopy-based navigation system

Concerns about the CT-based navigation system that involved a large extent of extra preoperational preparation including preoperative computed tomography with a specific protocol, data acquisition and transfer, and patient registration prevented this technique from being widely adopted [12, 40]. 2D FluoroNav appeared to solve the above problem. The equipment did not require registration; it reduced imaging time and radiation dosage, and avoided

Table 2 Description of included experimental studies

Study (year)	Study population (spinal level)	Interventions	Accuracy assessment	Conclusions
Choi et al. [40]	Six cadavers (T1–S1)	G1: CT Nav $n = 6$ (102 screws) G2: 2D FluoroNav $n = 6$ (106 screws)	CT + dissection	Accuracy provided by 2D FluoroNav is comparable to CT Nav, but requires less time
Ludwig et al. [47]	Twelve fresh frozen cadavers (C3–C7)	G1: CT Nav $n = 5$ (50 screws) G2: Abumi technique $n = 7$ (67 screws)	CT + dissection	Navigation system does not enhance accuracy compared with Abumi's technique
Ludwig et al. [47]	Twelve fresh frozen cadavers (C3–C7)	G1: Abumi technique $n = 4$ (40 screws) G2: laminoforaminiotomies + Abumi technique $n = 4$ (40 screws)	CT + dissection	Navigation system enhances accuracy of transpedicular screw placement, most notably at C6 and C7
Assaker et al. [44]	Eight human cadavers (four thoracic, four lumbar)	G3: CT Nav $n = 4$ (37 screws) G1: fluoroscopy $n = 4$ (40 screws) G2: CT Nav $n = 4$ (40 screws)	X-ray + CT	Navigated pedicle screw insertion is more accurate than conventional method, but more time consuming
Austin et al. [39]	Seven embalmed cadavers: Four simulating posterolateral fusion model and three simulating non-fusion model (T6–S1)	G1: fusion model; CT Nav $n = 2$ (24 screws) G2: fusion model; 2D FluoroNav $n = 1$ (12 screws) G3: fusion model; convention $n = 1$ (14 screws) G4: non-fusion model; 2D FluoroNav $n = 2$ (36 screws) G5: non-fusion model; convention $n = 1$ (14 screws)	CT + dissection	Navigation improves pedicle screw insertion accuracy, particularly the CT Nav, and especially relevant clinically when the anatomy is obscured or altered
Mirza et al. [41]	Twenty fresh frozen cadavers (thoracic)	G1: 2D FluoroNav multi-reference $n = 4$ (70 screws) G2: 2D FluoroNav single reference $n = 6$ (99 screws) G3: standard fluoroscopy $n = 6$ (94 screws) G4: CT Nav $n = 4$ (74 screws)	Anatomic dissection	A single reference-based 2D FluoroNav is highly inaccurate; systems with registration based on vertebrae are more accurate, but have more radiation exposure and more time is required
Sagi et al. [42]	Four fresh frozen cadavers (T1–T12)	G1: anatomic landmarks + fluoroscopy $n = 2$ (48 screws) G2: 2D FluoroNav $n = 2$ (48 screws)	Anatomic dissection	2D FluoroNav results in a similar incidence of safely placed screws as does conventional fluoroscopy, but reduced radiation exposure
Sagi et al. [43]	16 fresh frozen cadavers (L1–L5)	G1: anatomic landmarks $n = 6$ (60 screws) G2: fluoroscopy $n = 6$ (60 screws) G3: 2D FluoroNav $n = 4$ (40 screws)	Anatomic dissection	Usage of 2D FluoroNav in the lumbar spine results in improved accuracy, but requires increased time and does not decrease radiation exposure
Hart et al. [45]	Eight fresh cadavers (T1–T2, T4–T7, T9–T10)	G1: CT Nav $n = 4$ (64 screws) G2: fluoroscopy + manual technique $n = 4$ (64 screws)	CT + dissection	No significant difference in pedicle violation between navigated and conventional method
Tian et al. [49]	Thirty-two embalmed cadavers (C3–C7)	G1: blind screw placement $n = 8$ (80 screws) G2: conventional fluoroscopy $n = 8$ (78 screws) G3: 2D FluoroNav $n = 8$ (80 screws) G4: CT Nav $n = 8$ (80 screws) G5: 3D FluoroNav $n = 8$ (80 screws)	Anatomic dissection	Navigation enhances accuracies. 3D FluoroNav is the best among them

Table 2 continued

Study (year)	Study population (spinal level)	Interventions	Accuracy assessment	Conclusions
Arand et al. [11]	Nine spinal models (T6–T10, L1–L5)	G1: convention $n = 3$ (30 screws) G2: CT Nav $n = 3$ (30 screws) G3: 2D FluoroNav $n = 3$ (30 screws)	Visually inspecting	Navigation techniques are superior to conventional method
Xia et al. [51]	Four cadavers (T7–S1)	G1: convention $n = 2$ (48 screws) G2: 2D FluoroNav $n = 2$ (48 screws)	CT	2D FluoroNav improves the accuracy of pedicle screw placement
John et al. [46]	NO. Cadavers unstated (T1–T6)	G1: CT Nav (20 screws) G2: fluoroscopy (20 screws)	CT	CT Nav is superior to the conventional method in providing screw insertion accuracy
He et al. [50]	Ten cadavers (C2–C7)	G1: convention $n = 5$ (60 screws) G2: CT Nav $n = 5$ (60 screws)	CT + dissection	CT Nav provides higher but insignificantly different accuracy than conventional method
Von Jako et al. [54]	Four fresh frozen cadavers (T8–S1)	G1: convention $n = 2$ (40 K-wires) G2: 2D FluoroNav $n = 2$ (40 K-wires)	CT	2D FluoroNav can provide high-accuracy K-wire placement in percutaneous transpedicular procedures

repeated C-arm movements during surgery because visualization of the surgical instruments in relation to the patient's anatomy in all the desired image planes was possible from the beginning.

Two in vitro [11, 51] and four in vivo studies [15, 17, 33, 36] comparing the pedicle screw insertion accuracy between conventional and 2D FluoroNav methods indicated that such assistance could provide significantly more accurate pedicle screw placing (Fig. 1). Five in vitro papers also revealed that 2D FluoroNav obtained a lesser, but insignificant, perforation risk compared with the conventional methods (Fig. 1) [39, 41–43, 54].

Four cadaveric [12, 13, 15, 30], one model [11], and four in vivo studies [39–41, 49] have applied two navigation systems (CT Nav vs. 2D FluoroNav) in their researches. On further analysis, we found most studies [11–13, 30, 39–41, 49] implied that CT Nav obtained a lesser but insignificant risk compared with 2D FluoroNav (Fig. 2), which indicated that 2D FluoroNav obtained similar potential to CT Nav in pedicle screw insertion assistance.

Besides the better outcome obtained in the application of 2D FluoroNav in conventional spinal surgeries, the system has proved to be well used in revision surgeries, as assessed by Rampersaud et al. [53] who studied the accuracy of fluoroscopy-based navigation for the placement of thoracolumbar pedicle screws through a mature posterolateral fusion mass. Overall, 81.4% of screws were completely within the pedicle. Relative to the total number of screws, pedicle breaches were graded II (<2 mm) in 13.5%, III (2–4 mm) in 2.9%, and IV (>4 mm) in 2.0% of screws. The study indicated that the use of fluoroscopy-assisted navigation was safe and effective for the placement of thoracolumbar (T10–S1) pedicle screws through a posterolateral fusion mass without performing laminoforaminotomies [53]. Navigation systems provided the surgeon with a virtual “road map” of a patient's anatomy in relationship to the position of surgical instruments. Theoretically, it could be better used to assist minimally invasive surgery. von Jako et al. evaluated the accuracy and time efficiency of 2D FluoroNav compared with a conventional fluoroscopy method for percutaneous placement of Kirschner wires. A higher proportion of ideal trajectories were achieved in the 2D FluoroNav group. Moreover, the study indicated significant reduced screw placement times and shorter fluoroscopy times for the navigation group [54].

Three-dimension fluoroscopy-based navigation system

The 2D FluoroNav system provided only two-dimensional images, and there were no extra pictures in different reformatted plane that could be used intraoperatively to assist pedicle screw insertion. The development of 3D

FluoroNav appeared to combine the advantages of CT and 2D fluoroscopy-based assistances [12, 14–16]. Such a system provided three-dimensional images, as well as reduced extra preoperative preparation. Though studies on 3D FluoroNav were fewer than those on CT Nav or 2D FluoroNav, most studies indicated the potential advantage of 3D FluoroNav over the other two guiding systems. Like CT Nav, 3D FluoroNav provided intraoperative three-dimensional images, which could be used to assist pedicle screw insertion into abnormal pedicles or guide minimally invasive spinal surgeries. Rajasekaran et al. [18] carried out a randomized clinical trial to study the pedicle screw insertion accuracy with or without the assistance of 3D FluoroNav in patients with scoliosis or kyphosis. A total of 54 (23%) pedicle breaches were found in the non-navigation group as compared to only 5 (2%) in the navigation group ($P < 0.001$). Moreover, 38 screws (16%) in the non-navigation group had penetrated the anterior or lateral cortex compared to 2 screws (0.8%) in the navigation group [18]. The study also revealed that the navigation system reduced surgical time and radiation in thoracic deformity correction surgeries [18]. Nakashima et al. evaluated 300 percutaneous pedicle screws under assistance of either Iso-C three-dimensional navigation or conventional fluoroscopy. The difference in frequency of screw misplacement was statistically significant (Iso-C: 11/150 vs. fluoroscopy, 23/150; $P < 0.05$) [55].

The 3D FluoroNav possessed the advantage of both CT Nav and 2D FluoroNav; theoretically, it could gain better outcome compared with other navigation methods. In a large patient cohort study, 1,084 screws were placed with the assistance of either CT-based (perforation rate 9.2%) or 3D fluoroscopy-based navigation (perforation rate 6.6%) and the difference in breach rates between these two groups was statistically insignificant ($P = 0.0936$) [16]. A retrospective study comparing the 2D and 3D FluoroNav systems indicated that both systems were found to be comparably safe and accurate, and the choice of image-guidance modality may be determined by the level of surgeon comfort and/or availability of the system [14]. Gruetzner et al. [15] reported the remarkable improved precision of pedicle screw insertion with the assistance of 3D FluoroNav when compared with conventional, CT Nav and 2D FluoroNav methods. Moreover, they noted that the lowest average fluoroscopy time was achieved during the placement of pedicle screws on the spine with 3D FluoroNav at a comparable average operating room duration compared to the conventional approach and other computer-assisted procedures [15].

Other perioperative findings

Other than accuracy, spine surgeons also care about perioperative outcomes such as surgical time consumed,

radiation exposure, blood loss and patients' functional outcome. On comparing the navigated and conventional methods, most studies indicated that CTNav increased the time for spinal surgeries [15, 23, 26, 37, 41, 44]. This might be attributed to extra protocols such as preoperative images, modeling and simulation, and registration [12, 40, 57, 58]. One of the drawbacks of the CTNav is the considerable learning curve in the registration process. A quick registration requires an intimate knowledge of surgical anatomy and good cooperation between the surgeon and the navigation system [58]. FluoroNav that does not require registration might reduce surgical time. However, some authors pointed out that extra time was needed for the setup of the system, placing the transmitter and acquiring suitable images for navigation, which would not significantly reduce the total insertion time per screw [15, 17, 41–43].

CTNav needs preoperative CT scanning. The radiation exposure of the patients mainly depends on the CT protocol [59–61]. By analyzing the radiation of three different CT protocols-based navigation system, Slomczykowski et al. [59] noted that when CTNav was to be used, the spiral mode of CT scanning was recommended. Theoretically, FluoroNav could reduce the radiation running time compared with conventional fluoroscopy method, because such systems do not need repeated movement of the C-arm intraoperatively. In the prospective study conducted by Gebhard et al., 2D FluoroNav was found to produce less radiation than conventional C-arm, but more radiation than CTNav. Moreover, 3D FluoroNav was observed to have a further reduction of intraoperative radiation dosage compared with other navigation methods [59].

In the current review, navigational surgeries seemed not to significantly reduce blood loss compared with that without navigation assistance. A meta-analysis on functional outcome also indicated that navigation did not significantly reduce neurological complications and sufficient data were not available to draw a conclusion on other functional outcomes [56].

Conclusions

Compared to conventional methods, navigation provided a higher accuracy in the placement of pedicle screws. The superiority of navigation systems was obvious when they were applied to deformed spinal structure. Among the three different navigation methods, cumulative analysis implied that CT Nav provided a little higher accuracy than 2D FluoroNav subgroup, but provided a lower accuracy than the 3D FluoroNav subgroup.

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